



US008814928B2

(12) **United States Patent**
Robin

(10) **Patent No.:** **US 8,814,928 B2**
(45) **Date of Patent:** ***Aug. 26, 2014**

(54) **APPARATUS AND METHODS FOR REPAIRING ANEURYSMS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 66 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **12/616,928**

(22) Filed: **Nov. 12, 2009**

(65) **Prior Publication Data**

US 2010/0131040 A1 May 27, 2010

Related U.S. Application Data

(63) Continuation of application No. 10/481,386, filed as application No. PCT/GB02/02750 on Jun. 17, 2002, now Pat. No. 7,682,383.

(30) **Foreign Application Priority Data**

Jun. 19, 2001 (GB) 0114918.6

(51) **Int. Cl.**
A61F 2/06 (2013.01)
A61F 2/82 (2013.01)

(52) **U.S. Cl.**
USPC 623/1.21; 623/1.3; 623/1.35

(58) **Field of Classification Search**
USPC 623/1.3, 1.35, 1.11, 1.25, 1.21
See application file for complete search history.

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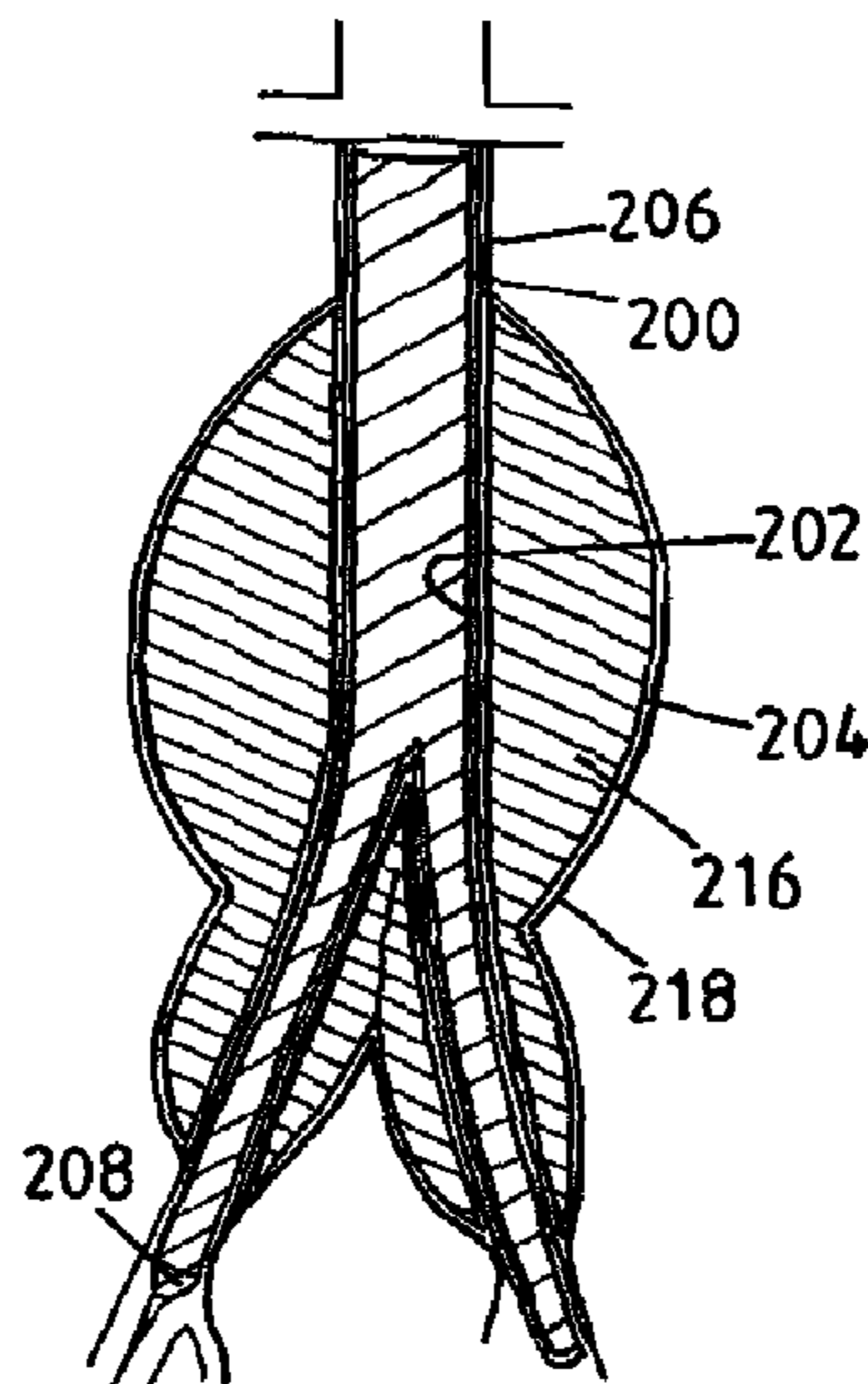
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Primary Examiner — Bruce E Snow

(57) **ABSTRACT**

An apparatus for repairing an aneurysm comprises a device having an inner graft tube and an inflatable outer balloon attached to an outer surface of the inner graft tube, and an inflatable deployment balloon. The inner graft tube is expandable within an artery to form a seal with the arterial wall above and/or below an aneurysm. The outer balloon is inflatable within the aneurysm with a rapidly settable substance to fill the aneurysm and support the device. The deployment balloon has an uninflated condition to fit within the inner graft tube and is inflatable within the inner graft tube to expand the inner graft tube within the artery and to maintain the inner graft tube expanded within the artery during inflation of the outer balloon.

4 Claims, 4 Drawing Sheets



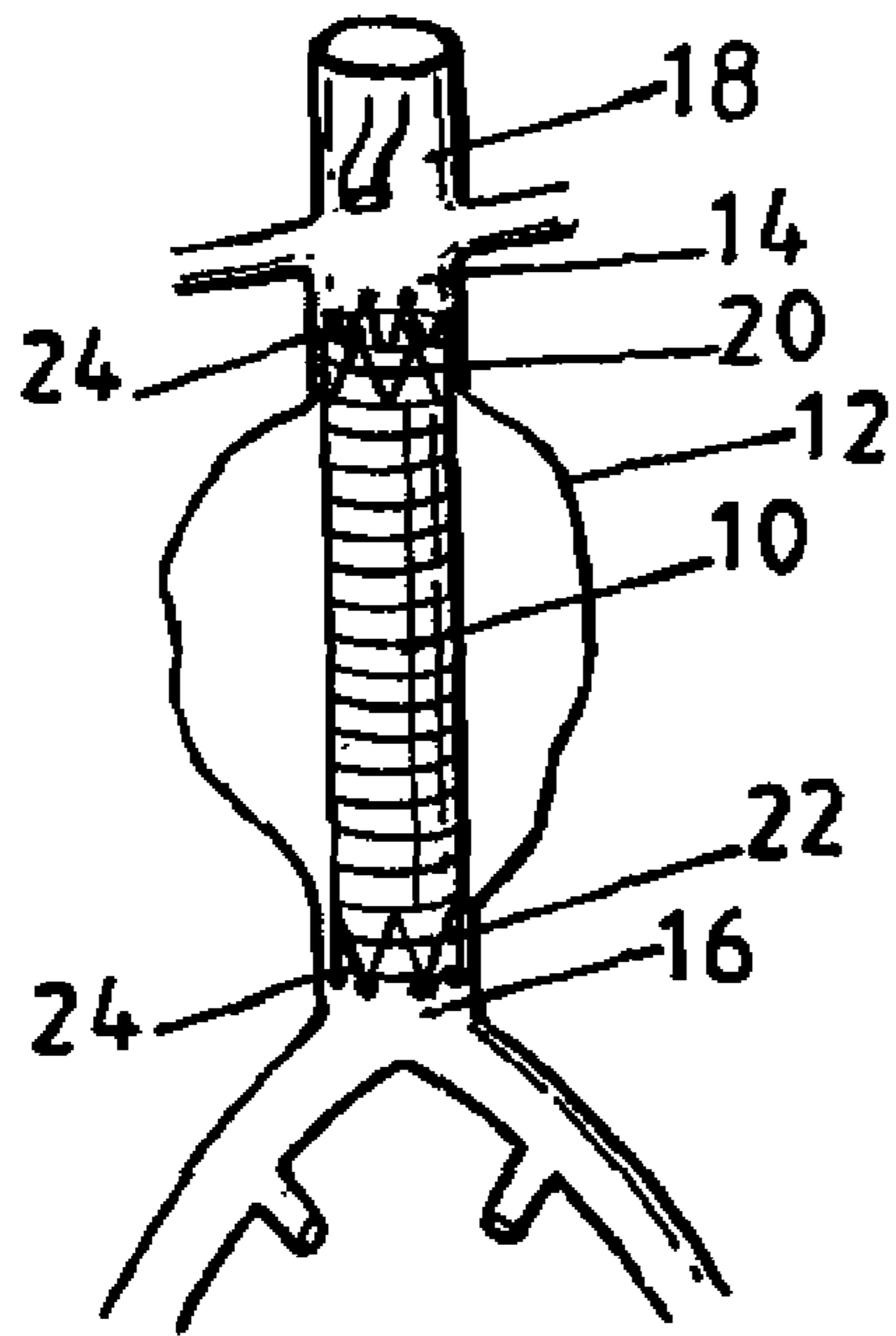


FIG. 1

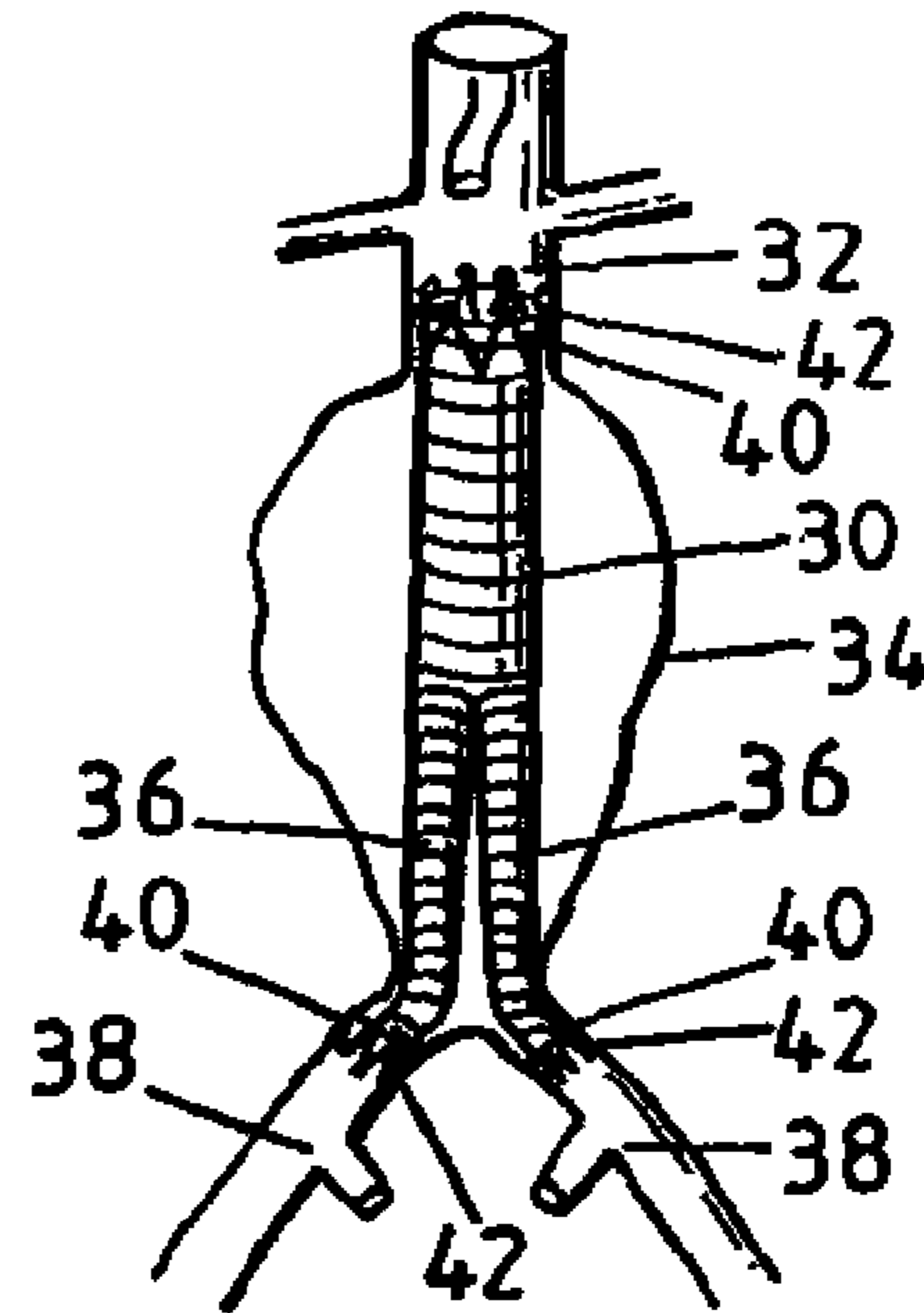


FIG. 2

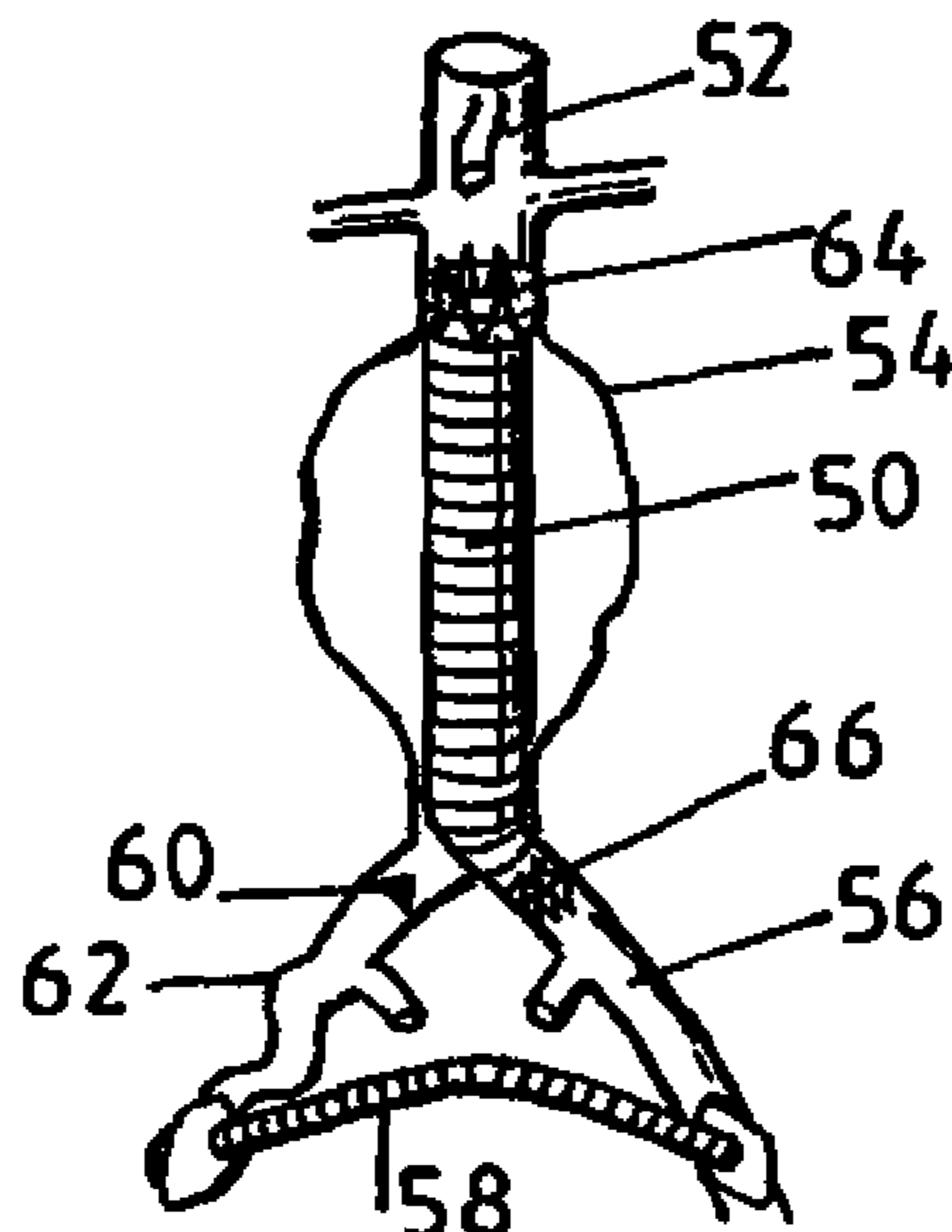


FIG. 3

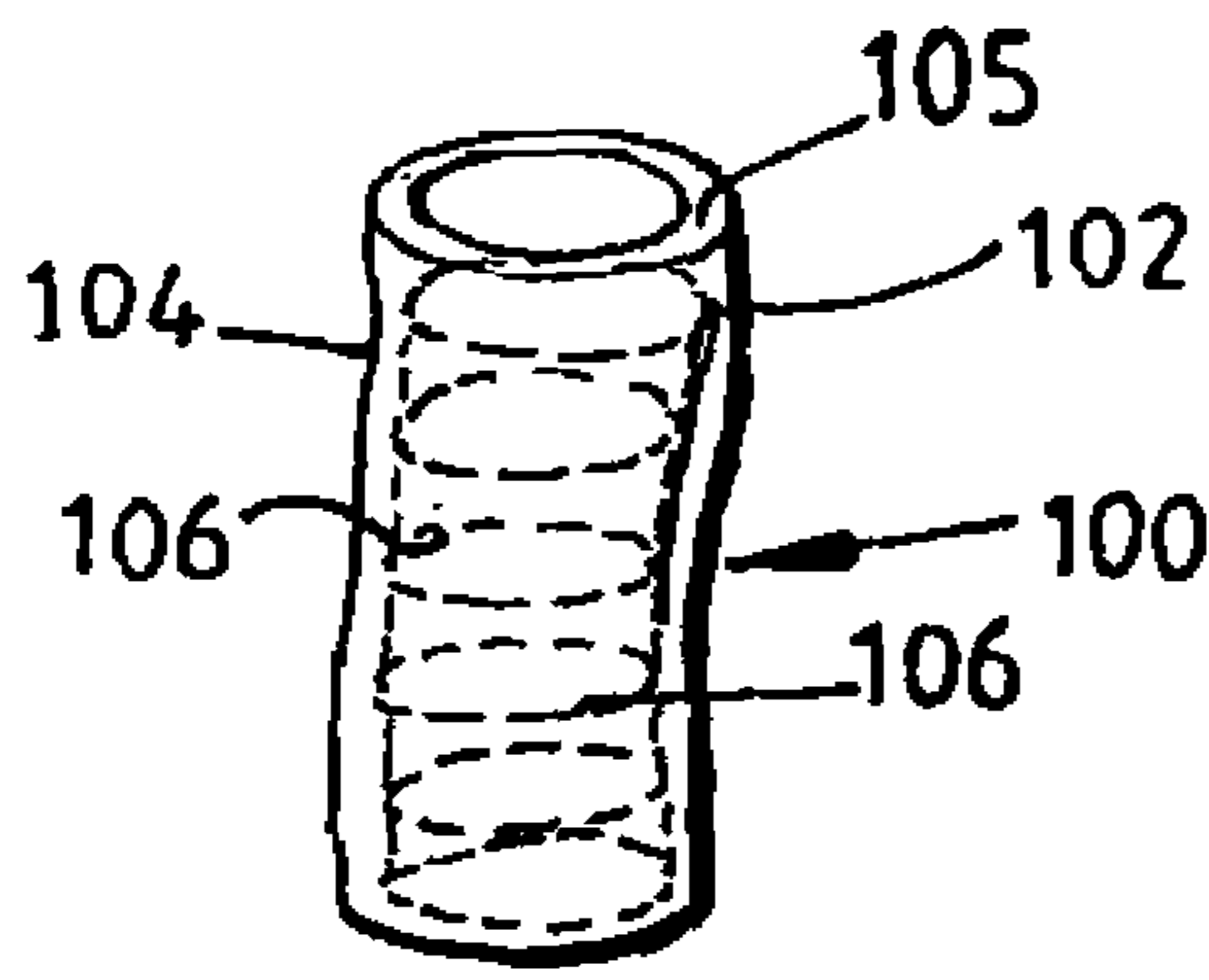


FIG. 4

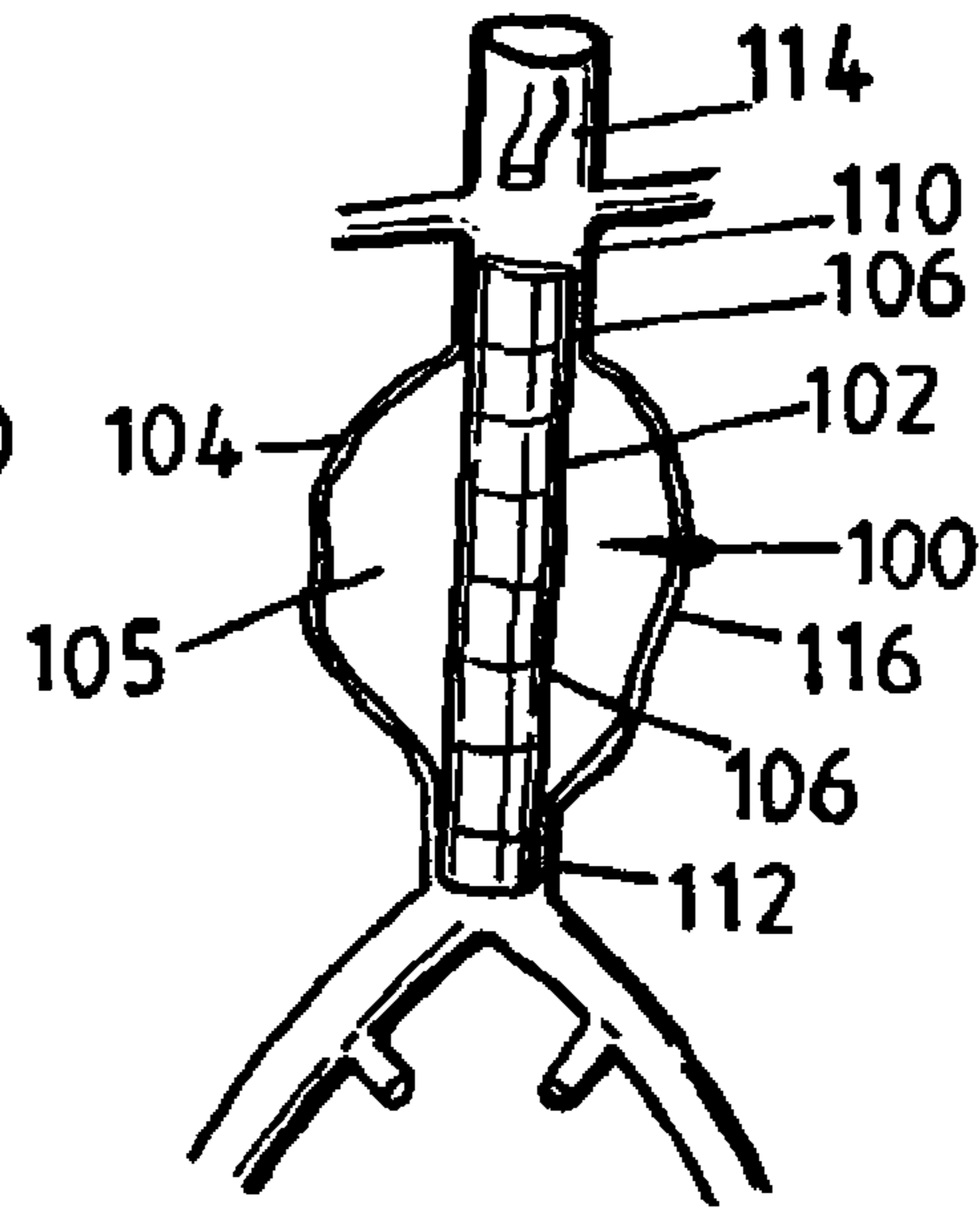


FIG. 5

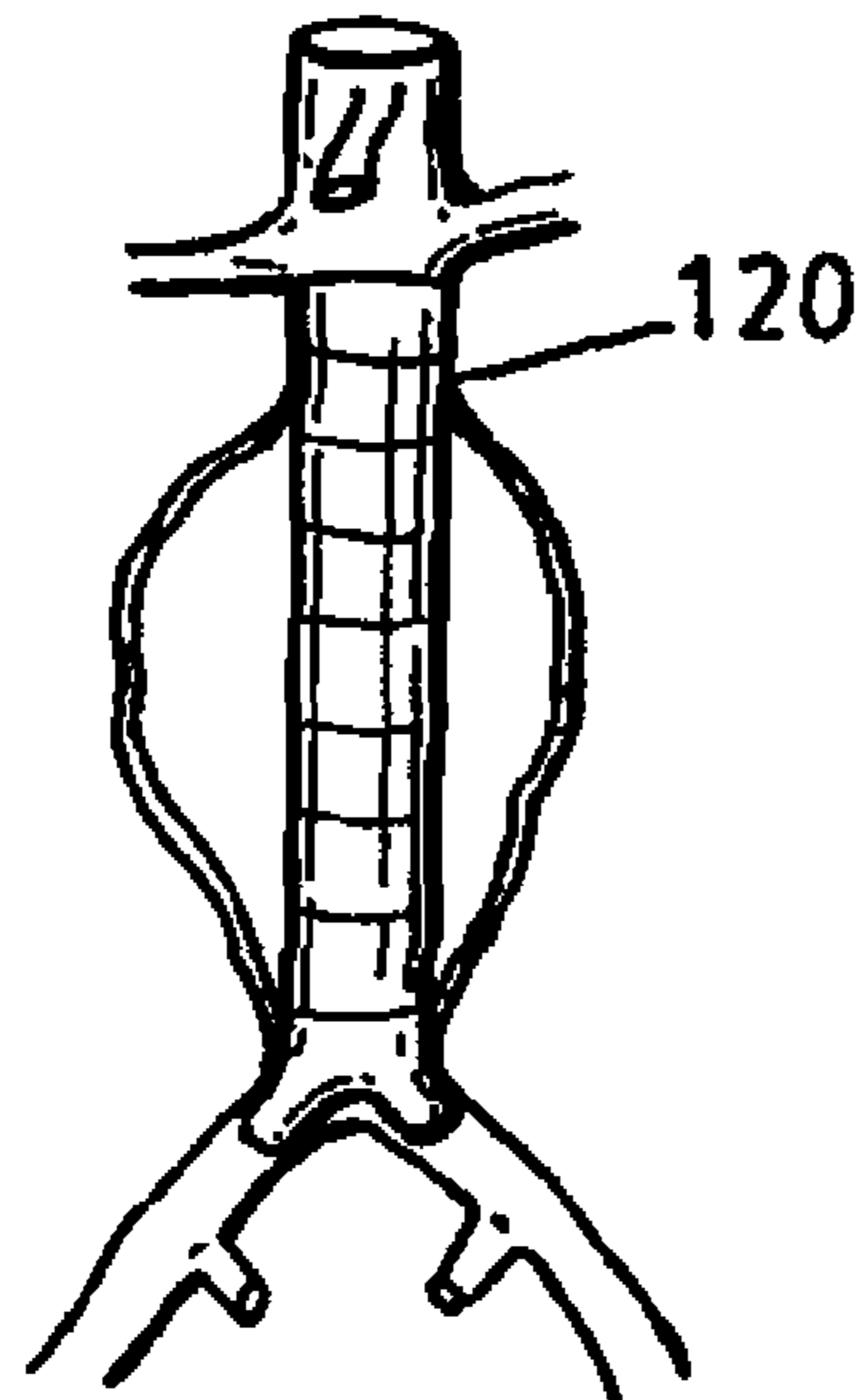


FIG. 6

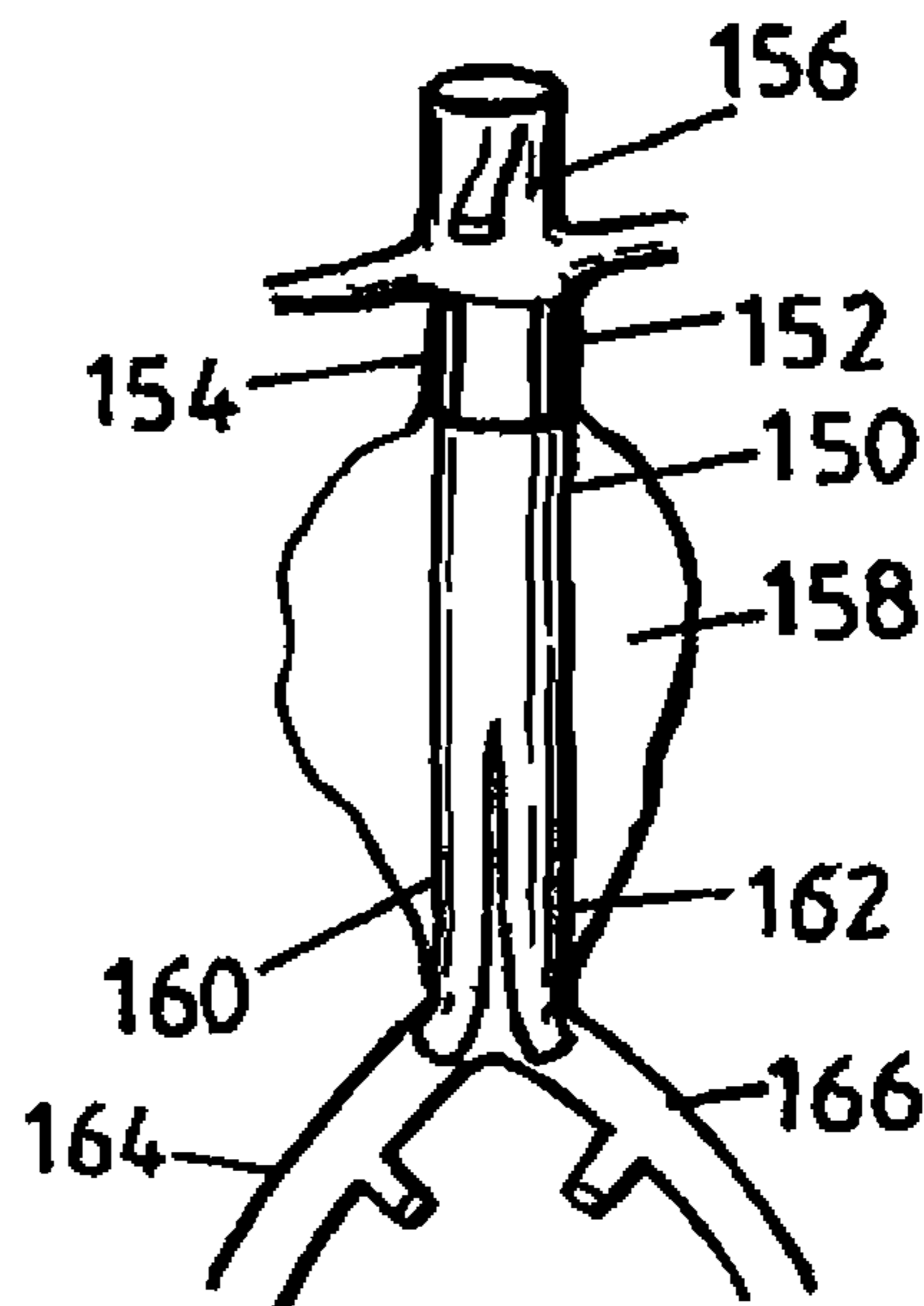


FIG. 7

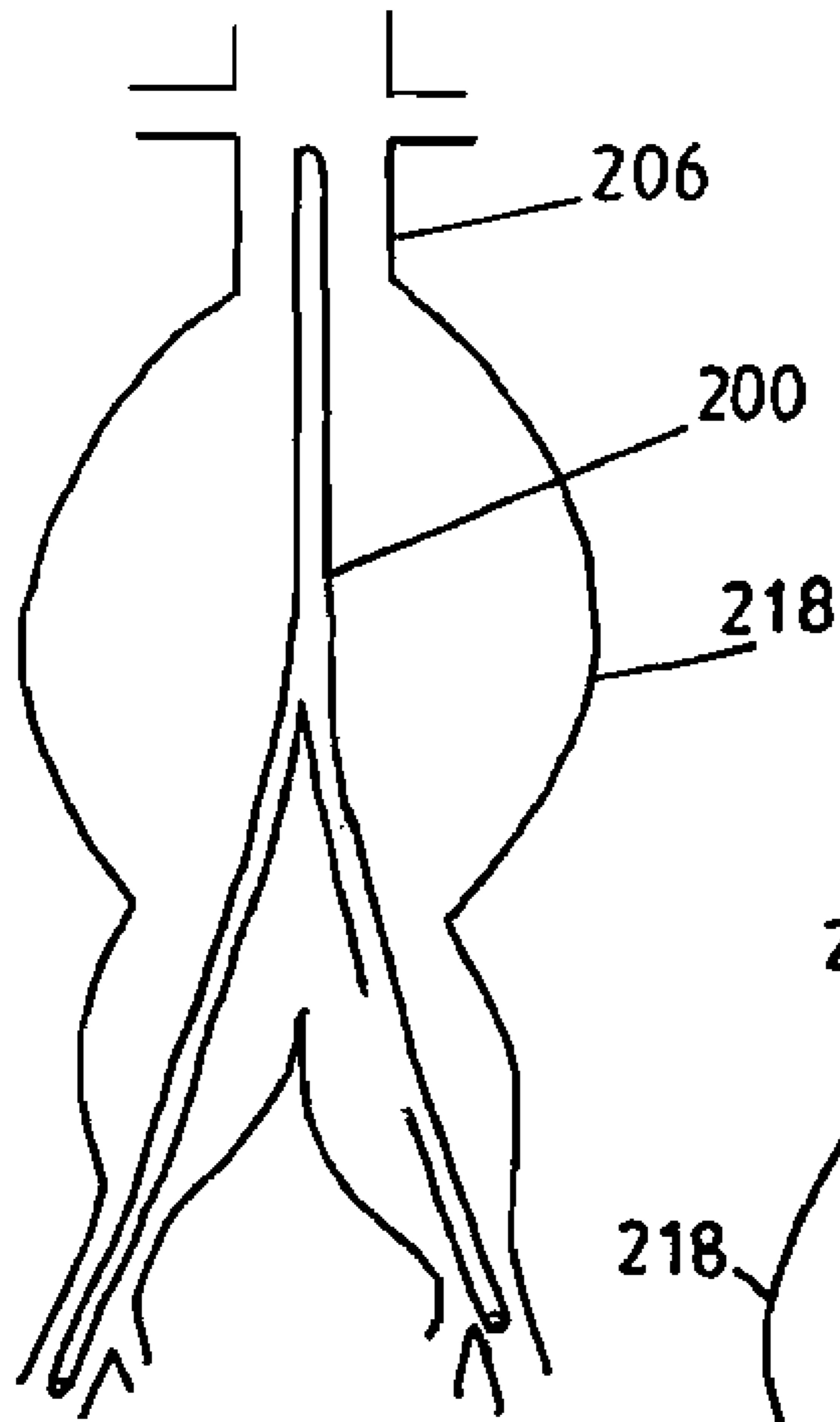


FIG. 8

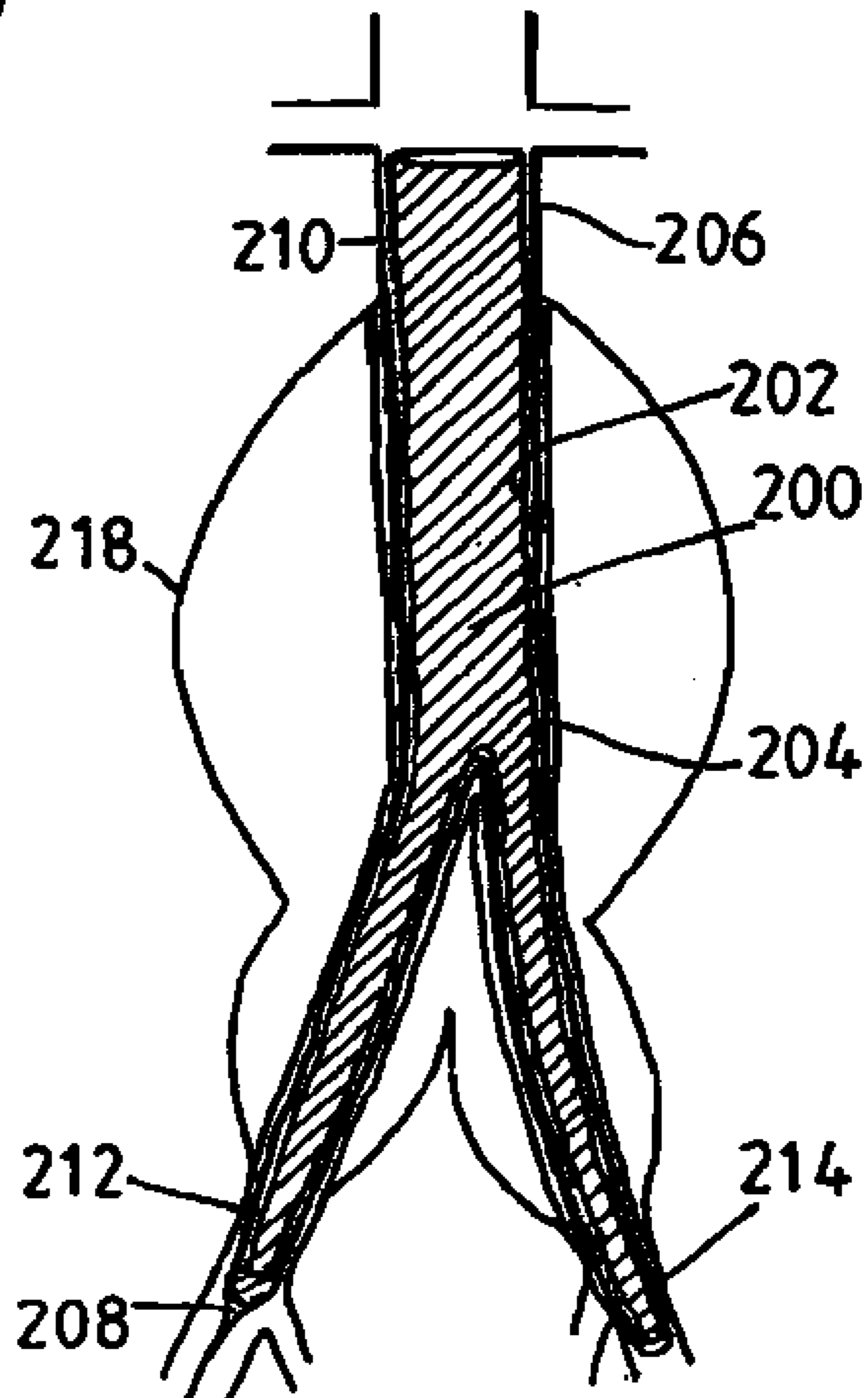


FIG. 9

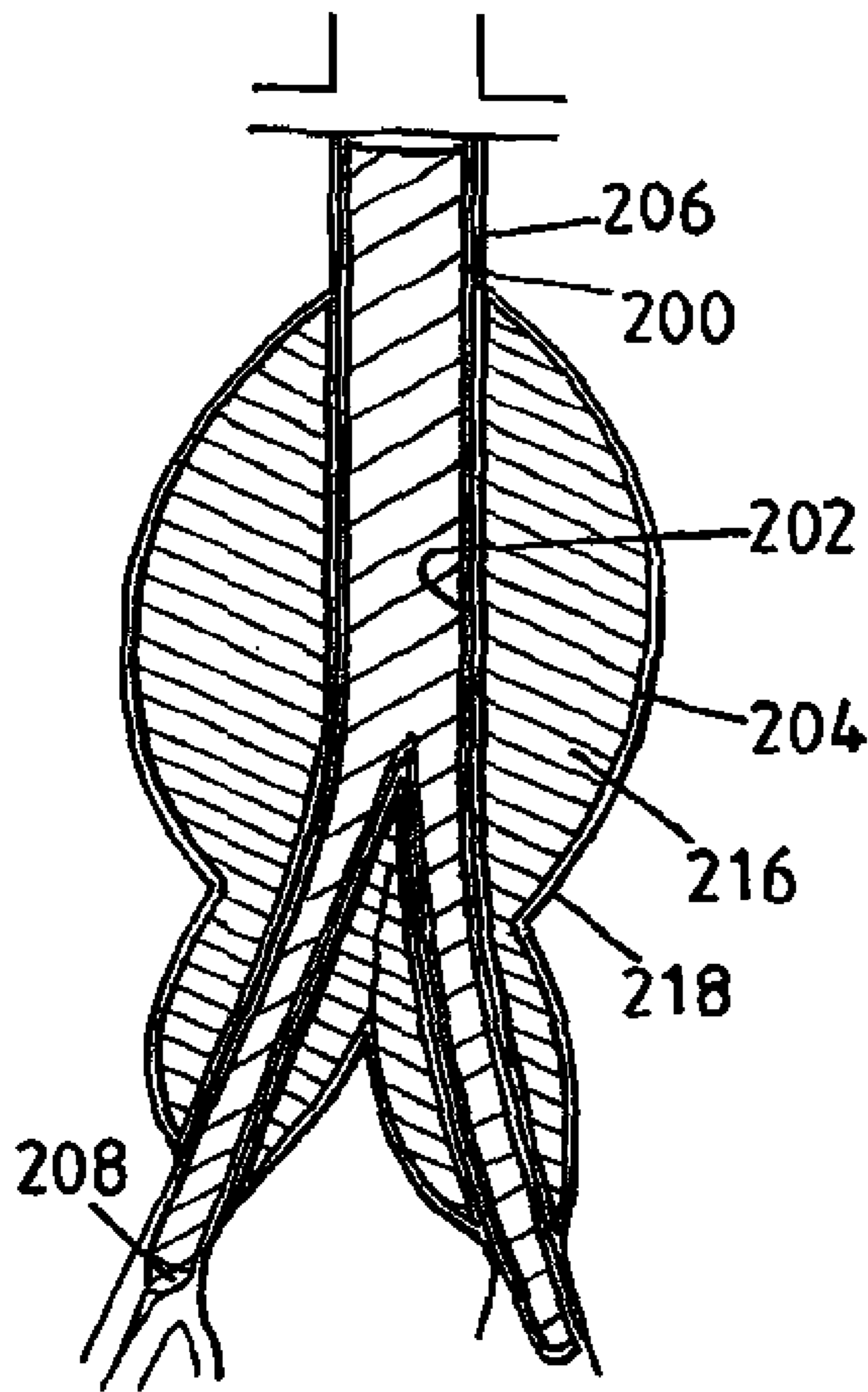


FIG. 10

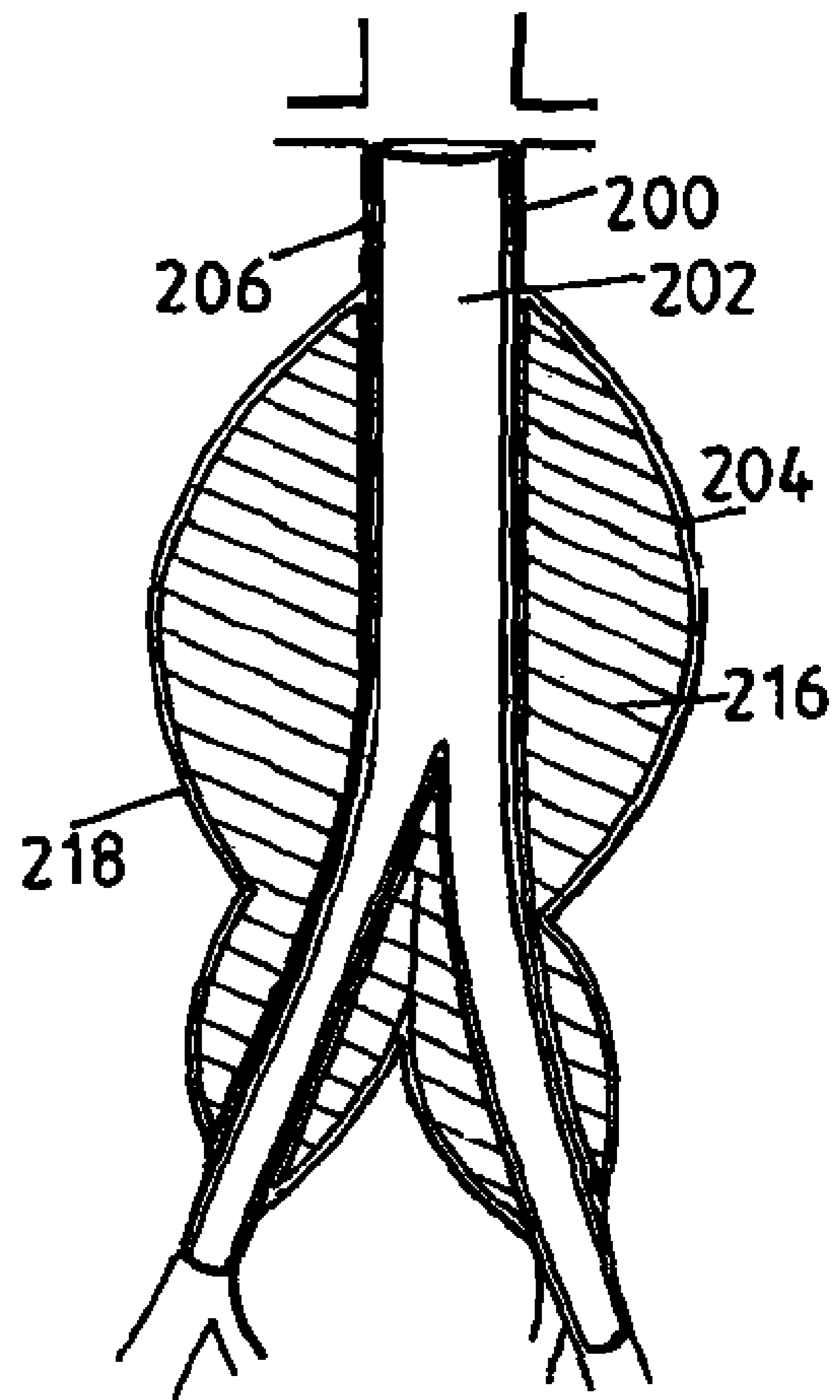


FIG. 11

APPARATUS AND METHODS FOR REPAIRING ANEURYSMS

CROSS-REFERENCE TO RELATED PATENT APPLICATIONS

This application is a continuation of prior U.S. patent application Ser. No. 10/481,386 filed Dec. 19, 2003 now U.S. Pat. No. 7,682,383, which claims priority from International Application No. PCT/GB02/02750 filed Jun. 17, 2002 and from Great Britain patent application No. 0114918.6 filed Jun. 19, 2001, the entire disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention concerns devices for use in repairing aneurysms, especially of the abdominal aorta.

2. Brief Discussion of the Related Art

An aneurysm occurs when an arterial wall becomes weakened to the extent that the weakened section balloons under pressure from the blood flowing through the artery. An aneurysm can lead to fatality if it ruptures causing rapid loss of blood.

An aortic aneurysm can be repaired by an endovascular repair procedure, in which a graft is inserted into the aneurysm via the femoral artery effectively to take the blood flow and to isolate the aneurysm. There are three forms of aortic endograft in current usage. The first is a straight stented tube graft. This may be used when there are adequate proximal and distal aortic necks for graft implantation. The tube may be stented at each end for support and to provide pins or hooks for embedding into the arterial wall to secure the tube in place. Alternatively, the tube may be stented throughout its length, such as by means of a metal wire stent. This form of endograft is used most commonly to repair aneurysms of the thoracic aorta.

An alternative construction of graft is a bifurcated tube for use in a patient with an abdominal aortic aneurysm where there is inadequate distal aortic neck but appropriate iliac artery configurations.

The third variation of endovascular graft is an aortouniliac graft, in which the tube extends from the proximal aortic neck into one of the iliac arteries. With this configuration an extraanatomic femofemoral bypass graft with a contralateral occlusion device in the common iliac artery is required. This device may be used when significant aneurysmal disease is present in the contralateral iliac artery, precluding successful bifurcated graft placement.

A problem with such grafts is that over time, even over a period of two years, the graft can slip due to wear and tear on the stents, the effect of pulsatile blood flow through the tube and changes in the morphology of the arteries. The blood flow effect can be exaggerated as the graft slips and is able to bend and flex. Thus over time the integrity of the graft and isolation of the aneurysm can be compromised.

Another problem with stented grafts is that the twisting or flexing of the graft can cause fatigue in the metal stent. Such fatigue leads to fracturing of the stent wire and the resultant wire ends can pierce the graft material. Holes in the graft material mean that the aneurysm is no longer isolated from the blood flow.

Such grafts are generally used in a planned manner with the graft being selected for a specific patient according to precise pre-operative measurement of the aorta and adjacent arteries. Therefore, such grafts are not readily suited for use in repair-

ing a ruptured aneurysm, where an emergency procedure is required simply to prevent death.

SUMMARY OF THE INVENTION

An object of this invention is to provide a device for use in repairing aneurysms that does not suffer from the above-mentioned disadvantages.

According to this invention there is provided a device for repairing an aneurysm by deployment within the aneurysm, the device comprising a graft tube, at least part thereof having an inflatable wall, whereby the tube can be deployed in an artery and be inflated to contact at least part of the arterial wall.

The term arterial wall may include arterial wall that is undamaged and/or aneurysm wall.

Graft tubes of the invention may be made of any suitable biologically compatible material and especially of plastics material.

Graft devices of the invention may be straight tubes or bifurcated tubes for use depending on the position and size of the aneurysm, i.e. for deployment in a similar manner to conventional endograft graft tubes. The graft tube of this embodiment may be one that narrows from one end to the other for use in aortouniliac grafting. The device of the invention may have an inflatable wall along its entire length or the device may have one or more discrete inflatable sections, especially at one or more ends of the tube.

Preferably the inflatable wall of the graft tube has an inner wall and an outer wall that is expandable in preference to the inner wall. The inner wall may be reinforced compared to the outer wall. Reinforcements of the inner wall may be, for example, by means of hoops, cages or mesh. Reinforcements may be of metal or plastics. Suitable metal reinforcement materials include stainless steel and nickel-titanium alloy. Suitable plastics reinforcement materials include inert polymers, such as, for example, polytetrafluoroethylene. Alternatively, the inner wall may be of a different material to the outer wall or may be of the same material but of different thickness to achieve the desired effect of the outer wall expanding upon inflation in preference to the inner wall with the inner wall substantially retaining its shape. The inflatable wall of the tube is preferably inflated by insertion of a settable material. Preferably the material is introduced as a liquid and sets to a solid or semi-solid state. The inflating material used will be biologically compatible and may, for example, be based on collagen or temperature/pH sensitive hydrogels, such as N-isopropyl acrylamide. It is possible that for stented graft tubes the inflating material need only set to a pliable condition. However, if the graft tube of the invention is to be deployed using a balloon to prevent an un-reinforced inner wall collapsing while the inflatable wall is being inflated, the inflating material may need to set to a relatively rigid condition.

The tube may be deployed in an aneurysm by inflating the tube, so that at least at the proximal artery position and ideally also at the distal artery position the tube grips the walls of the artery where there is no wall damage and between those positions the outer wall of the tube expands to contact the walls of the aneurysm and thereby support the aneurysm against flexing.

In one embodiment of the invention, a graft tube for use in repairing arterial aneurysms may have a first part with an inflatable wall to fit into the neck of the artery above an aneurysm. The remainder of the graft can be a straight, tapered or bifurcated tube.

Grafts of the invention may be deployed in an aortic aneurysm by means of conventional endovascular techniques. Typically, a guide wire is inserted through the femoral artery to extend beyond the aneurysm and the graft is guided into position along the wire. A narrow tube for inflating the twin walled part of the graft will be incorporated into the graft, one end of which will be accessible for the purpose of injection within the access wound in the groin. Once inflated to a desired extent the inflation tube is sealed.

Additionally or alternatively, a graft according to the invention may be deployed with the aid of an inflatable deployment balloon. Thus, a graft of the invention may be positioned in an aneurysm in collapsed form mounted on a deflated deployment balloon. The deployment balloon can then be inflated to seal the graft to the arterial wall above and below the aneurysm before the outer part of the graft is inflated by means of the settable material to conform to the anatomy of the aneurysm. Finally, the deployment balloon is deflated and withdrawn.

BRIEF DESCRIPTION OF THE DRAWINGS

This invention will now be further described, by way of example only, with reference to the accompanying drawings, in which:

FIG. 1 shows a first prior art aortic aneurysm repair technique;

FIG. 2 shows a second prior art aortic aneurysm repair technique;

FIG. 3 shows a third prior art aortic aneurysm repair technique;

FIG. 4 shows a first graft according to the invention;

FIG. 5 shows the graft of FIG. 4 in position in an aortic aneurysm;

FIG. 6 shows a second graft according to the invention in position in an aortic aneurysm;

FIG. 7 shows a third graft according to the invention in position in an aortic aneurysm;

FIG. 8 shows a first stage of deployment of a fourth graft according to the invention;

FIG. 9 shows a second stage in the deployment of the fourth graft according to the invention;

FIG. 10 shows a third stage in the deployment of the fourth graft according to the invention; and

FIG. 11 shows a fourth stage in the deployment of the fourth graft according to the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. 1 of the accompanying drawings, a tubular graft **10** is shown deployed in an aortic aneurysm **12**. The aneurysm is situated between proximal and distal regions **14,16** respectively of the aorta **18**. This deployment is possible when there is adequate aortic tissue above and below the aneurysm for attachment of the graft. The graft is stented (**20,22**) at each end and has pins **24** extending from the stented regions for attachment to the aortic wall.

When there is inadequate aortic tissue below an aortic aneurysm for attachment of a graft as shown in FIG. 1 of the drawings, a bifurcated graft **30** can be used as shown in FIG. 2. Here the graft is attached in the neck **32** of the aorta above the aneurysm **34** and the two tube **36** resulting from the bifurcation are each deployed in an iliac artery **38** below the aneurysm. Again the ends of the graft are stented (**40**) and pins **42** are provided to aid attachment to the artery walls.

If there is significant aneurismal disease in the contralateral iliac artery, which precludes use of a bifurcated graft of the type shown in FIG. 2, a graft **50** as shown in FIG. 3 may be used, which is deployed between the aorta **52** above the aneurysm **54** and the healthier iliac artery **56**. The graft tube **50** narrows to compensate for the difference in widths of the aorta and iliac artery. With this procedure an extraanatomic femofemoral bypass **58** is required with a contralateral occlusion device **60** in the common iliac artery **62**. Again this graft **50** is stented at both ends (**64,66**).

Turning now to FIGS. 4 and 5 of the accompanying drawings, there is shown a tubular endovascular graft **100** of the invention for use in repairing an aortic aneurysm. The graft **100** is twin-walled having an inner wall **102** and an outer wall **104**, whereby the space **105** between the walls can be inflated by introduction of inflating material.

The outer wall **104** is relatively expandable compared to the inner wall **102**. Both walls may be of the same material but the inner wall reinforced, so that upon inflation, the outer wall expands to contact the aneurysm wall, as shown in FIG. 5, whilst the inner wall **102** retains substantially its diameter, so as not to affect adversely blood flow through the graft. The inner wall **102** as shown is reinforced with metal hoops **106**, although the reinforcement can be of other materials or take a different form. An alternative may be to make the inner and outer walls of different materials to achieve a similar effect.

The graft **100** can be deployed in a similar manner to the graft shown in FIG. 1, i.e. between proximal and distal regions **110,112** respectively of the aorta **114** above and below the aneurysm **116**. When in position the graft is inflated by introduction of inflating material. This causes the outer wall of the graft to expand, firstly to grip the walls of the artery in those proximal and distal regions to fix the graft in place and secondly to contact the walls of the aneurysm to provide support therefor and, in the case of rupture, to seal the leakage of blood by direct closure of the tear in the aneurysm wall.

The inflating material is preferably a biocompatible material and may, for example, be based on collagen or temperature/pH sensitive hydrogels, such as N-isopropyl acrylamide. Preferably the inflating material is one that can be introduced as a liquid but which sets to form a pliable mass, such as in the nature of a gel. Once sufficient inflating material is introduced into the graft, possibly through a valve, the inflated graft is sealed.

In FIG. 6, a bifurcated graft **120** is shown which is similar in nature and general use to the graft **100** of FIGS. 4 and 5 but for the type of situation shown in FIG. 2 of the drawings, i.e. where there is aortic tissue damage requiring iliac artery deployment.

In FIG. 7 of the accompanying drawings there is shown an alternative form of inflatable tubular graft **150**. The graft shown is a bifurcated graft but only a top portion **152** thereof is twin-walled. Thereby the graft **150** can be deployed and the top portion **152** inflated as with other embodiments of the invention to fix the graft in the proximal neck **154** of the aorta **156** above the aneurysm **158**. The iliac tubes **160,162** of the graft may be fixed in the iliac arteries **164,166** in a conventional manner.

Turning to FIGS. 8 to 11 of the accompanying drawings, an endograft **200** comprises an inner graft tube **202** and an outer inflatable balloon **204** attached to the inner tube. The endograft shown is bifurcated but it could also be a single stem straight or tapered endograft. The outer balloon is designed to be inflated to conform to the anatomy of an aneurysm.

The endograft **200** is delivered into aorta **206** in a collapsed state mounted over an inflatable deployment balloon **208**.

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Once the endograft is in position, the deployment balloon is inflated to expand the graft to form seals at the anastomoses **210**, **212** and **214** of the aorta and iliac arteries (see FIG. **9**). As seen in FIGS. **9** and **10**, the deployment balloon **208**, when inflated, supports the inner graft tube **202** along at least substantially the entire length of the inner graft tube **202**. With the deployment balloon **208** still inflated, the outer balloon **204** of the endograft is inflated with a substance that rapidly sets to form a solid mass **216**. Once that substance has set, the deployment balloon is deflated and removed, leaving the endograft supported by the inflated outer balloon that has conformed to the contours of the aneurysm sac **218**.

Fixation of the endograft can then be enhanced by placement of stents (with or without barbs or hooks), which secure the upper and lower extremities of the graft to the surrounding arterial wall.

Advantages of grafts according to the invention include the possibility of rapid deployment, which, in the case of a ruptured aneurysm is vital, because the graft does not have to be designed for a particular patient. The ability to inflate the graft to fix it in place means that the same type of graft can be used in a variety of cases. The gel material used to inflate the device, by filling the aneurysm sac, will stabilise the endograft and prevent buckling, migration and leaking over time. The effects of post-operative changes in the morphology of the aneurysm sac and adjacent blood vessels will also be minimised with improved long-term stability of the repair.

Another possible advantage of graft devices of the invention is that they can be deployed without the need for stents, which means that the stent fatigue problem can be avoided.

The endografts of the invention are primarily intended for planned treatment of aneurysms but may also be used for emergency sealing of a ruptured aneurysm as a holding manoeuvre to stabilise a critically ill patient. Extensions and modifications may be made at a later date using additional inflatable or conventional endografts overlapping within the lumen of the first inflatable endograft using the "trombone" technique.

Inflated devices of the invention can seal aortic side branches and thereby completely isolate an aneurysm from systemic blood pressure.

The invention claimed is:

1. A method of repairing an aneurysm by deploying within an aneurysm and adjacent normal artery a device comprising

- a. an inner graft tube and an inflatable outer balloon attached to an outer surface of the inner graft tube,

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- i. the inner graft tube having an unexpanded condition and the inflatable outer balloon having an uninflated condition allowing deployment of the device in an artery at the location of an aneurysm,
- b. the method comprising the steps of
 - i. delivering the device to the aneurysm on an inflatable deployment balloon having an uninflated condition to fit within the inner graft tube in the unexpanded condition, said step of delivering including delivering the device to the aneurysm with the inner graft tube in the unexpanded condition and the deployment balloon in the uninflated condition within the inner graft tube,
 - ii. inflating the deployment balloon to expand the inner graft tube within the artery from the unexpanded condition to an expanded condition to contact the wall of the artery above and/or below the aneurysm to form a seal with the wall of the artery above and/or below the aneurysm,
 - iii. inflating the outer balloon within the aneurysm from the uninflated condition to an inflated condition with a rapidly settable substance to entirely fill the aneurysm and conform to the anatomy of the aneurysm while the inflated deployment balloon remains within the inner graft tube to maintain the inner graft tube in the expanded condition within the artery,
 - iv. deflating and removing the deployment balloon from the inner graft tube upon setting of the settable substance, and
 - v. leaving the device in the artery with the inner graft tube in the expanded condition and the outer balloon in the inflated condition.

2. A method according to claim **1**, wherein at least one stent is placed to further secure the inner graft tube to the wall of the artery above the aneurysm and/or at least one stent is placed to further secure the inner graft tube to the wall of the artery below the aneurysm so as to enhance the seal between the inner graft tube and the wall of the artery above and/or below the aneurysm.

3. A method according to claim **1**, wherein the rapidly settable substance is introduced into the outer balloon via a tube incorporated into the device.

4. A method according to claim **1**, wherein the rapidly settable substance is introduced into the outer balloon as a liquid and rapidly sets to a solid or semi-solid state.

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